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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,724	09/22/2000	Pramod K. Srivastava	8449-128-999	1804

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/668,724

Applicant(s)

SRIVASTAVA, PRAMOD K.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,32,71 and 75-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,32,71 and 75-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 & 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The examiner of the application has changed. This case has now been transferred. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Christopher Yaen, Group Art Unit 1642.

Election/Restrictions

2. Applicant's election without traverse of group IV in Paper No. 8 is acknowledged. Amendments to claims 31 and 71 have been entered, newly added claims 75-84, will be considered, and claims drawn to non-elected groups have been canceled without prejudice. Claims 31-32, 71, and 75-84 are examined on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 31-32, 71, and 75-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. In regards to claims 31 and 71, and dependent claims thereof, in the recitation of the terms "*modulating*" and "*modulates*", it is unclear as to what type of modulation is intended to, is it an increase or is it a decrease in the amount of immune response. Clarification is required.

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6. In regards to claim 75 and 76 in the recitation of the term "*activity*", it is unclear as to what type of activity is to be either increased (claim 75) or decreased (claim 76) following the interaction of a compound that modulates or binds to α 2M receptor.

Clarification is required.

7. In regards to claim 83 in the recitation of the phrase "*small molecule*", it is indefinite and unclear as to the exact meaning of this phrase, because the metes and bound of this phrase cannot be determined. Clarification is required.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 31, 32, 71, 75, 77-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for modulation in terms of decreasing the binding of a ligand to α 2m receptor and hence affecting receptor activity does not reasonably provide enablement for modulation in terms of increasing the binding of a ligand to a α 2m receptor and hence affecting receptor activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 31,32,71,75,77-84 are drawn to methods of modulating an immune response comprising administering a compound that modulates the interaction of a HSP with an α 2m receptor (claims 31, 77-84) or binds to α 2m receptor in an amount effective to modulate an immune response. The instant specification envisions the use

of both agonists and antagonists, but is silent with regard to how an agonist is to work or function as a modulator of an increase in receptor activity. Because the specification has not taught one of skill in the art how to make, use, screen, or determine what type of activity is required, it forces the skilled artisan to experiment.

⁶ The factors which must be considered in determining undue experimentation are set forth in In re Wands 8 USPQ2d 1400. The factors include: (1) quantity of experimentation, (2) the amount of guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the predictability of the art and, (7) breadth of the claims.

With regards to factors one and two cited above, the quantity of experimentation needed to determine, discover, test and analyze compounds that are capable of modulating by increasing receptor activity, is high, because, the skilled artisan would not know where to begin looking for such compounds, the amounts needed to accomplish claimed invention, and the quantities that are required to effectively practice the claimed invention. The instant specification is virtually silent in this regard and is thus not seen as adequate guidance in the written description for accomplishing and determining such.

With regards to factors four, five and six cited above, it is noted that there is a great deal of unpredictability associated in a method of modulating the immune response by increasing receptor activity through the use of any compound or agonists. ⁶ The instant specification fails to provide details as to which agonists are capable of providing the desired effect.

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⁶ With regards to factors three and six cited above, it is noted that the working example is limited to the discovery of HSP- α 2M receptor interaction. Such is not seen as sufficient to support the breadth of the claims, wherein the scope of the claims encompasses modulation in general, wherein receptor activity can either be an decrease or increase in receptor activity. The specification has only provided an enabling disclosure for compounds that can bind to α 2m receptor, wherein the binding decrease the receptor activity.

10. Claims 75 and 76 rejected under 35 U.S.C. 112, first paragraph, because the ⁶ specification, while being enabling for activities associated ligand binding to a α 2m receptor, does not reasonably provide enablement for activities other than receptor-ligand interactions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 75 and 76 are drawn to methods of modulating an immune response by either increasing (claim 75) or decreasing (claim 76) α 2m-receptor activity. The instant ⁶ specification describes receptor activities in terms of ligand interaction with receptor, but has not described activities outside of ligand-receptor binding interactions. Because the specification is silent in this regard, it forces the skilled artisan to experiment.

With regard to factors one and two cited above, the quantity of experimentation associated with determining receptor activities such as downstream effects of ligand binding to receptor, is high because the skilled artisan may be forced to determine outcomes, effects, and reactions not readily known in the art. Such is not seen as

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adequately providing guidance in the written description for accomplishing and determining such.

With regards to factors four, five and six cited above, it is noted that there is a great deal of unpredictability associated with determining receptor activities. The instant specification fails to provide to one of skill in the art the necessary steps and procedures to determine which activities are required determine of an adequate modulation of receptor activity has been achieved.

With regards to factors three and seven cited above, it is noted that the examples provided in the instant specification is limited to the discovery of HSP- α 2M receptor interaction. Such is not seen as sufficient to support the breadth of the claims, wherein the scope of the claims encompasses receptor activities in general, beyond receptor-ligand binding interactions. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art ho to use applicant's alleged discovery, not how to find out how to use it for themselves., see In re Gardner et al. 166 USPQ 138 (CCPA 1970).

Claim Rejections - 35 USC § 102

11. If the scope of enablement rejection made above is over-come with regard to agonists, the following rejection under 35 USC§102 can be applied.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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⁶ (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 71, 76, 83, 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Pizzo *et al.* (IDS CT). Claims 71, 76, 83, and 84 are drawn to a method of modulating an immune response by administering a compound, wherein the compound binds to α 2M receptor, wherein the compound is an agonist or antagonist which increases or decreases α 2M receptor activity respectively, wherein the compound is a small molecule or a peptide. Pizzo *et al.* disclose of a compound, an antigen- α 2M complex, that is able to modulate an immune response. Inherently, once a molecule binds to α 2M receptor, it either increases or decrease the receptor activity, and hence modulates the receptor, therefore, any agonist or antagonist that is able to bind to α 2M receptor would modulates the receptor either by increasing or decreasing activity of the α 2M receptor. In addition, Pizzo *et al.* also disclose of small molecules, and peptides. Because receptors are generally larger than 40 kDa, a molecule that is small relative to a receptor would be smaller than or equal to 40kDa, and since peptides can be an amino acid sequence of any length smaller than a full protein, the complex of antigen- α 2M disclosed in the Pizzo *et al.* can therefore be considered a peptide. These claims are therefore anticipated by Pizzo *et al.*

Conclusion

No claims are allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
May 6, 2002


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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